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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,117	10/14/2003	Peter M. Bonutti	782-A03-009-3	4436
33771	7590	12/22/2004	EXAMINER	
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L. 601 BRICKELL KEY DRIVE, SUITE 404 MIAMI, FL 33131			JACKSON, GARY	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/685,117	Applicant(s) BONUTTI, PETER M.	
	Examiner Gary Jackson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/14/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION***Double Patenting***

Claims 1-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,238,395 since if allowed, would improperly extend to the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a bone suture assembly for treating a fracture of a bone comprising: a first bone plate positioned proximate to the bone; and a suture positioned through the first bone plate and across the fracture of the bone to thereby stabilize the fracture. The allowance of this claim would extend the rights to exclude already granted in claims 1-14 of the patent—that "right to exclude" covering an introducer comprising: a method of treating a fractured bone having a compact outer layer which encloses cancellous bone, said method comprising the steps of forming a passage which extends through the compact outer layer on a portion of the bone disposed on a first side of the fracture, through the cancellous bone on opposite sides of the fracture, and through the compact outer layer on a portion of the bone on a second side of the fracture, positioning a tubular member in the passage with a first end portion of the tubular member in engagement with the compact outer layer on the portion of the bone on the first side of the fracture, with a second end portion of the tubular member in engagement with the compact outer layer on the portion of the bone on the second side of the fracture, and with a portion of the tubular member disposed between the first and second end portions of the tubular member in engagement with the cancellous bone on opposite sides of the fracture, positioning a force transmitting member in the

Art Unit: 3731

passage with at least a portion of the force transmitting member in the tubular member, and transmitting force through the force transmitting member to urge the portions of the bone on the first and second sides of the fracture toward each other while at least a portion of the force transmitting member is disposed in the tubular member.

The transitional phrase "comprising" does not exclude the presence of elements other than: a bone suture assembly for treating a fracture of a bone comprising: a first bone plate positioned proximate to the bone; and a suture positioned through the first bone plate and across the fracture of the bone to thereby stabilize the fracture. The patent also would inherently cover the method of using the device. Because of the phrase "comprising" the patent claim not only provides patent coverage to the method already disclosed and covered by the issued patent. Thus the controlling fact is that the patent protection for the device is fully covered by the claim of the patent, would be extended by the allowance of the claim in this application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3731

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 13-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by McQuilkin et al (US Patent 5,219,359). McQuilkin et al is discloses the same structural limitation as recited in the claims above and it is capable of being used in the manner recited. See figure 1.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce (US Patent 4,823,794). Figure 3 of the reference discloses implants and a suture having limitations as recited in the claims immediately above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3731

Claims 8-12 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corriveau et al (US Patent 5,366,480) in view McQuilkin et al or Pierce. The patent to Corriveau et al discloses the limitations of the above claims except that it does not disclose a second implant. It would have been obvious to one having ordinary skill in the art to provide Corriveau et al with a second implant as taught by Pierce or McQuilkin et al to add stability to the tissue. Concerning claim 8-10 at the least the tubular portion of Corriveau et al will contain protein (bone particles) where blood and other tissue enter from the suture holes. The passage per se has no patentable weight in this instance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (571) 272-4697. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Antoine Nguyen can be reached on (571) 272-4693. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Jackson
Primary Examiner
Art Unit 3731



gj
December 20, 2004